

P20257.A12

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : H. SUSAKI et al.

Group Art Unit: 1614

Serial No. : 09/674,526 ✓

(US National Stage of (PCT/JP99/02681))

Examiner: Russell

Filed : November 21, 2000

For : DRUG COMPLEX



RESUBMISSION OF INFORMATION DISCLOSURE STATEMENTS

Commissioner of Patents
PO Box 1450
Alexandria, VA 22313-1450

Sir:

Further to our facsimile of April 1, 2004, please find enclosed signed copies of the Information Disclosure Statement filed May 9, 2001 and the Supplemental Information Disclosure Statement filed June 5, 2001, including copies of the cited documents, accompanied by date stamped mailroom receipts evidencing filing of the same.

Should the Examiner have any questions, please contact the undersigned at the telephone number provided below.

Respectfully submitted,
H. SUSAKI et al.

Bruce H. Bernstein
Reg. No. 29,027

April 6, 2004
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191

P20257.A03

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : H. SUSAKI et al.

Serial No. : 09/674,526

Group Art Unit : Not Known

Filed : November 21, 2000

Examiner : Not Known

For : DRUG COMPLEX

INFORMATION DISCLOSURE STATEMENT

Commissioner of Patents and Trademarks
Washington, D.C. 20231

Sir:

In accordance with the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97, and 1.98, Applicants hereby bring the following information to the attention of the Examiner in charge of the above-identified application, which includes information cited in International Application No. PCT/JP99/02681, including the description, International Search Report and International Preliminary Examination Report. Copies of the above-noted document were filed when entering the National Stage on November 21, 2000, and the Examiner is referred to these documents relating to the relevance of the cited information.

JP 6-87746, accompanied by an English language abstract;

JP 11-92405 A accompanied by an English language abstract

WO 92/14759, which is family member of JP 7-84481 B;

WO 94/19376, for the convenience of the Examiner attached is a U.S. family member U.S.

Patent No. 5,688,931;

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WO 97/46260

Abstracts of 10th Meeting of the Japan Society of Drug Delivery System, pp. 279 (1994);

Abstracts of 9th Annual Meeting of Japanese Society for the Study of Xenobiotics, pp. 292 (1994);

Abstracts of 19th Seminar of Trends in Research and Development, pp. D-9 - D-12 (1995);

Abstracts of 12th Colloid and Interface Technology Symposium, The Chemical Society of Japan, pp. 51-58 (1995);

Gene M. Dubowchik et al., "Monomethoxytrityl (MMT) as a Versatile Amino Protecting Group for Complex Prodrugs of Anticancer Compounds Sensitive to Strong Acids, Bases and Nucleophiles", Tetrahedron Letters, Vol. 38, No. 30, pp. 5257-5260 (1997); and

Gene M. Dubowchik et al., "Efficient Mitomycin C Coupling With Stable p-Nitrophenyl-Benzyl Carbonates Using N-Hydroxybenzotriazole as a Catalytic Additive", Tetrahedron Letters, Vol. 38, No. 30, pp. 5261-5264 (1997);

Applicants also bring the following documents to the attention of the Examiner:

WO 98/13059;

Gene M. Dubowchik et al., "Cathepsin B-Sensitive Dipeptide Prodrugs.1. A Model Study of Structural Requirements for Efficient Release of Doxorubicin", Bioorganic & Medicinal Chemistry Letters, Vol. 8, pp. 3341-3346 (1998);

COPY

Gene M. Dubowchik et al., "Cathepsin B-Sensitive Dipeptide Prodrugs.2. Models of Anticancer Drugs Paclitaxel (Taxol®), Mitomycin C and Doxorubicin", Bioorganic & Medicinal Chemistry Letters, Vol. 8, pp. 3347-3352 (1998);

P20257.A03

Franciscus M.H. de Groot et al., "Synthesis and Biological Evaluation of Novel Prodrugs of Anthracyclines for Selective Activation by the Tumor-Associated Protease Plasmin", J. Med. Chem., Vol. 42, pp. 5277-5283 (1999);

Ion Niculescu-Duvaz et al., "Self-Immolative Anthracycline Prodrugs for Suicide Gene Therapy", J. Med. Chem., Vol. 42, pp. 2485-2489 (1999);

Dan Niculescu-Duvaz et al., "Self-Immolative Nitrogen Mustard Prodrugs for Suicide Gene Therapy", J. Med. Chem., Vol. 41, pp. 5297-5309 (1998);

Richard B. Greenwald et al., "Drug Delivery Systems Employing 1,4- or 1,6-Elimination: Poly(ethylene glycol) Prodrugs of Amine-Containing Compounds", J. Med. Chem., Vol. 42, pp. 3657-3667 (1999);

Yu-Ling Leu et al., "Design and Synthesis of Water-Soluble Glucuronide Derivatives of Camptothecin for Cancer Prodrug Monotherapy and Antibody-Directed Enzyme Prodrug Therapy (ADEPT)", J. Med. Chem., Vol. 42, pp. 2623-2628 (1999); and

Ruben G.G. Leenders et al., "Novel Anthracycline-spacer- β -glucuronide, - β -glucoside, and - β -galactoside Prodrugs for Application in Selective Chemotherapy", Bioorganic & Medicinal Chemistry, Vol. 7, pp. 1597-1610 (1999).

Copies of the above-noted documents are enclosed together with a duly completed Form PTO-1449. The Examiner is accordingly requested to consider each of these documents, and to make them of record in this application by initialing in the appropriate spaces on the Form PTO-1449. Applicant respectfully requests that the Examiner include a copy of the initialed Form PTO-1449 with the next communication from the U.S. Patent and Trademark Office.

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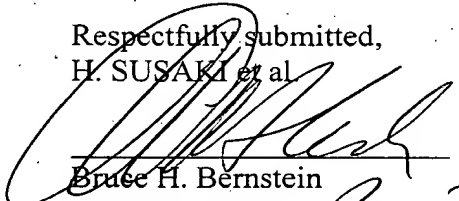
Applicants also bring to the Examiner's attention commonly assigned U.S. Application No. 09/147,342 (a copy of which is enclosed), which is a National Stage of PCT/JP97/01914, filed June 5, 1997, and which published as the above-noted WO 97/46420.

If any fees are necessary for consideration of this disclosure statement, the Commissioner is authorized to charge any required fee to Deposit Account No. 19-0089.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

May 9, 2001
GREENBLUM & BERNSTEIN, P.L.C.
1941 Roland Clarke Place
Reston, VA 20191
(703) 716-1191

Respectfully submitted,
H. SUSAKI et al.


Bruce H. Bernstein
Reg. No. 29,027

Jan 33098

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5/09/2001

File In: Mailroom

The Patent Office Date stamp hereon is an acknowledgement that, on the date indicated, the Patent Office received the following:

- | | |
|--|--|
| <input type="checkbox"/> Amendment _____ | <input type="checkbox"/> Claim of Priority & Certified Copy of _____ |
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<input type="checkbox"/> by facsimile | |
| <input type="checkbox"/> Executed S.E.S. <input type="checkbox"/> S.E.S. Assertion | <input type="checkbox"/> Declaration <input type="checkbox"/> Supplemental |
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| <input type="checkbox"/> Letter to Draftsman | _____ pages (w/abstract) |
| <input type="checkbox"/> Design Patent Application Transmittal | _____ claims _____ independent |
| <input type="checkbox"/> Utility Patent Application Transmittal | _____ sheets of drawings |
| <input type="checkbox"/> Provisional Application Cover Sheet | _____ figures |
| <input type="checkbox"/> Continued Prosecution Application | <input checked="" type="checkbox"/> I.D.S. form PTO-1449 & |
| (CPA) Request Transmittal | References <input checked="" type="checkbox"/> as attached |
| <input type="checkbox"/> Request for Continued Examination (RCE) | <input type="checkbox"/> as listed on reverse |
| including Submission | <input type="checkbox"/> One self-addressed postcard |
| <input type="checkbox"/> Cover Letter | <input type="checkbox"/> Certification under 1.97(e) |
| <input type="checkbox"/> Check No. _____ for \$ _____ | <input type="checkbox"/> Certificate of Mailing (C-O-M) |
| <input type="checkbox"/> Rule 53b and 53f Letter for | <input type="checkbox"/> Returned Envelope |
| Unexecuted Application | <input checked="" type="checkbox"/> Copy of US patent app. No. 09/147,342 |



In the matter of : DRUG COMPLEX

COPY

Applicant : Hiroshi SUSAKI
 Kazuhiro INOUE
 Hiroshi KUGA

Application No. : 09/674,526

Patent No. :

Filed : 2/13/2001

Issued :

Docket : P20257

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Form PTO-1449

U.S. Department of Commerce
Patent and Trademark OfficeAtty. Docket No.
P20257Serial No.
09/674,526INFORMATION DISCLOSURE STATEMENT
BY APPLICANT
(Use several sheets if necessary)Applicant
H. SUSAKI et al.Filing Date
November 21, 2000Group
1614

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	5 6 8 8 9 3 1	11/18/97	NOGUSA et al.			

FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO
6 - 8 7 7 4 6	03/29/94	JAPAN			
1 1 - 9 2 4 0 5	04/06/99	JAPAN			
9 2 / 1 4 7 5 9	09/03/92	W. I. P. O.			
9 4 / 1 9 3 7 6	09/01/94	W. I. P. O.			
9 7 / 4 6 2 6 0	12/11/97	W. I. P. O.			
9 8 / 1 3 0 5 9	04/02/98	W. I. P. O.			

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

1	English Language Abstract of JP 6-87746.
2	English Language Abstract of JP 11-92405.
3	Abstracts of 10th Meeting of the Japan Society of Drug Delivery System, pp. 279 (1994).
4	Abstracts of 9th Annual Meeting of Japanese Society for the Study of Xenobiotics, pp. 292 (1994).
5	Abstracts of 19th Seminar of Trends in Research and Development, pp. D-9 - D-12 (1995).
6	Abstracts of 12th Colloid and Interface Technology Symposium, The Chemical Society of Japan, pp. 51-58 (1995).
7	Gene M. Dubowchik et al., "Monomethoxytrityl (MMT) as a Versatile Amino Protecting Group for Complex Prodrugs of Anticancer Compounds Sensitive to Strong Acids, Bases and Nucleophiles", Tetrahedron Letters, Vol. 38, No. 30, pp. 5257-5260 (1997).
8	Gene M. Dubowchik et al., "Efficient Mitomycin C Coupling With Stable p-Nitrophenyl-Benzyl-Carbonates Using N-Hydroxybenzotriazole as a Catalytic Additive", Tetrahedron Letters, Vol. 38, No. 30, pp. 5261-5264 (1997).

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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INFORMATION DISCLOSURE STATEMENT
BY APPLICANT
(Use several sheets if necessary)

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

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